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10/517,626	07/28/2005	Gian Luca Araldi	SNI-003US	3939

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EXAMINER

NOLAN, JASON MICHAEL

ART UNIT	PAPER NUMBER
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1626

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,626	Applicant(s) ARALDI ET AL.	
	Examiner Jason M. Nolan, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-46 and 49-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18-46, 49-55 and 59-93 is/are rejected.
- 7) ☒ Claim(s) 56-58 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-16, 18-46 & 49-93 are pending in the instant application; of which, **Claims 1, 5, 7, 8, 10, 13-16, 51, 55, 59 & 60** are currently amended and **Claims 61-93** are new.

Response to Amendments and Arguments

Applicant's amendments, see Amendment – After Non-Final Rejection, filed 04/06/2007, with respect to **Claims 1, 5, 7, 8, 10, 13-16, 51, 55, 59 & 60** have been fully considered and are entered. The amendments to said claims do not overcome the prior art rejection of Elworthy *et al.* (WO 2003008377 A1, 01/30/2003; see US Patent **6,900,336**; priority to US Provisional Serial No. 2001-305,727, filed on 7/16/2001; see IDS). The amendment to **Claim 51** overcomes the 112-enablement rejection and said rejection has been withdrawn. The amendment to **Claim 55** does not clarify the drawing with respect to the dotted line; therefore the objection is maintained.

Applicant's argument with respect to **Claim 54** has been fully considered but is not convincing. Elworthy *et al.* teaches a method of treating a disease in a mammal that is treatable by administration of a selective EP4 prostaglandin agonist, (see **Claim 24** of the '336 patent), and Applicant admits that the compounds in **Claims 55-60** are prostaglandin EP4 receptor agonist, (see preamble in **Claim 55**). Further, a fertility condition in a female would fall under the term sexual dysfunction, listed in column 1 of the '336 specification.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 16, 18-46, 49-55, 59, 92 & 93 are rejected under 35 U.S.C. 102(e) as being anticipated by Elworthy *et al.* (WO 2003008377 A1, 01/30/2003; see US Patent **6,900,336**; priority to US Provisional Serial No. 2001-305,727, filed on 7/16/2001; see IDS). Taught in the reference is a family of compounds comprising a pyrrolidinone core, wherein the nitrogen is substituted with an alkyl, alkyl-aryl, or alkyl-heteroaryl; and the 5-position of the core contains hydroxy substituted alkene (see previous Office Action). Further, compound RN 493036-24-1 is part of the disclosure (said compound directly anticipates the instantly claimed invention).

The pharmaceutical compositions of the '**336** Patent are useful for the treatment of a disease in a mammal that is treatable by the administration of a selective EP₄ prostaglandin agonist (**Claims 23-25**), such as those mentioned in the specification in columns 1 & 2.

In **Claims 1-4**: wherein one of **V** and **Q** is hydrogen and the other is $-\text{CR}^1\text{R}^2-\text{W}$ and **W** is C₁-C₆ alkyl, the compound RN 493036-24-1 directly anticipates.

In **Claim 16**, compound RN 493036-24-1 directly anticipates the first species listed.

In **Claims 55 & 59**: wherein **Q** is $-\text{CR}^4\text{R}^5-\text{W}$ and **W** is C₁-C₆ alkyl, the compound RN 493036-24-1 directly anticipates.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-12, 14-16 & 60-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elworthy *et al.* (WO 2003008377 A1, 01/30/2003; see US Patent 6,900,336; priority to US Provisional Serial No. 2001-305,727, filed on 7/16/2001; see IDS), taken alone.

Determination of the scope and content of the prior art (MPEP § 2141.01)

Taught in the reference is a family of compounds comprising a pyrrolidinone core, wherein the nitrogen is substituted with an alkyl, alkyl-aryl, or alkyl-heteroaryl; and the 5-position of the core contains a hydroxy substituted alkene, (see formula I in **Claim 1** of the '336 Patent). Further, compound RN 493036-24-1 is included in the disclosure (said compound directly anticipates the instantly claimed invention).

The pharmaceutical compositions of the '336 Patent are useful for the treatment of a disease in a mammal that is treatable by the administration of a selective EP₄ prostaglandin agonist (**Claims 23-25**), such as those mentioned in the specification in columns 1 & 2.

Therefore, the scope and content of the prior art correlate significantly to the instant application.

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

Claim 5 and dependent **Claims 6-12, 15, 16 & 60** (in part: some of the species), and the corresponding methods of **Claims 61-91** have been amended (or added) such that when **V** and/or **Q** may be a substituted alkyl (and therefore not unsubstituted) or –

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CR^1R^2-W , wherein W is propyl, pentyl, or substituted C_1-C_6 alkyl. With these considerations, if V is H and Q is CR^1R^2-W , wherein R^1 & $R^2 = H$ and W is propyl or pentyl, the difference between such compounds and compound RN 493036-24-1 is a methylene group. Therefore, the instant claims describe a homologous series of compounds of RN 493036-24-1. Furthermore, there are a plethora of such hypothetical compounds that are fully supported by formula I in Elworthy *et al.* due to the significant overlap.

Finding of prima facie obviousness--rational and motivation (MPEP § 2142-2413)

To those skilled in the chemical art, one homolog is not such an advance over an adjacent member of a series because chemists knowing properties of one member of the series would, in general, know what to expect in adjacent members. *In re Henze*, 85 USPQ 261 (1950). The instant claims as a whole would have been obvious to one of ordinary skill in the art because they teach either homologs to RN 493036-24-1 or a subgenus of compounds that directly overlap with the formula I of Elworthy *et al.* One of ordinary skill in the art would have been motivated to prepare homologs of the compounds taught by Elworthy *et al.* with the expectation of obtaining compounds with similar properties.

Claim Objections

Claims 13 & 16 (in part: some species therein, i.e. the 8th species on page 7) are objected to because a branched alkyl group is still an unsubstituted alkyl group. For instance, said species comprises a "3-hydroxy-6-methylhept-1-enyl" moiety, which is an unsubstituted branched alkyl. Therefore, said claims do not include every limitation of the claim from which they depend, (see Claim 1, wherein **V** and **Q** may be a *substituted* alkyl).

Claims 16 & 60 are objected to because of the following informalities: the word "and" should be inserted between the last two species in each list.

Claim 55 is objected to because of the following informalities: The drawing of formula VI still contains what looks like a double bond (at variable **B**), and the bond is referred to as a dotted line in the text of the claim. For clarification, please attempt further correction of said drawing.

Claims 56-58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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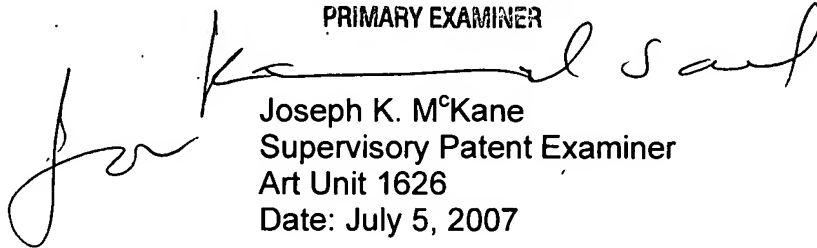
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356** and electronic mail is **Jason.Nolan@uspto.gov**. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph M^cKane** can be reached on **(571) 272-0699**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Date: July 5, 2007